
•Standards for the Coverage of Organ Transplant Services

I. STANDARDS FOR ORGAN TRANSPLANTATIONS

- A. Only medically necessary, non-experimental transplantations are covered by AHCCCS. AHCCCS will assume no financial responsibility for any costs, direct or indirect, generated by any experimental procedure.

AHCCCS closely monitors guidelines set forth by the Health Care Financing Administration and the Food and Drug Administration as well as national and community standards of care when making determinations as to whether a drug or a procedure is experimental or non-experimental. AHCCCS maintains transplant committees composed of specialists in the various transplant fields. These specialists/committees meet on a regular basis to review outcomes and respective changes in technology, and, are available for consultation as necessary. Services and procedures are not covered until approved by the AHCCCS Administration in consultation with Health Plan/Program Contractor Medical Directors following careful review of all information obtained from these resources.

- B. Transplantation services must be provided in a HCFA certified and/or United Network Organ Sharing (UNOS) approved transplant center that is contracted with AHCCCS, unless otherwise approved by the member's health plan or program contractor, and the AHCCCS Medical Director. The surgery must be done by a surgical team experienced in the transplantation surgery being performed.

- C. The AHCCCS Health Plan or Program Contractor is responsible for verification of Title XIX eligibility for members, providing written prior authorization for the transplantation and for providing AHCCCS with timely medical documentation of the appropriateness of the transplantation.

For Title XIX members who are not enrolled with a Health Plan or Program Contractor, the AHCCCS Medical Director must provide written prior authorization for the transplantation. The contracted transplant facility is responsible for providing timely medical documentation of the necessity of the transplantation.

D. Out-of-Network Coverage

AHCCCS provides out-of-state and/or out-of-network coverage for major organ or bone marrow transplants for those members who have current medical requirements that cannot be met by an appropriate in-network transplant center. These medical requirements must be manifested as requiring either a specific level of technical expertise or program coverage that is not currently provided by AHCCCS contracted

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facilities. Members must not have received a medical denial (due to not being an appropriate candidate for the transplant) from an approved transplant center prior to requesting the procedure out-of-network.

In addition, the requested transplant procedures and/or surgeries must:

1. Be considered non-experimental and confirmed as such by a consensus of current, well-controlled studies, and reliable evidence and medical literature that demonstrate outcome results comparable, or superior to, recognized conventional therapies;
2. Be a recognized standard of care in the medical community; and
3. Have approval from the appropriate AHCCCS medical expert transplant committee.

Expenses for follow-up services related to transplants performed out-of-state will be the member's responsibility if the follow-up services are available through an AHCCCS contracted in-state facility. These expenses include but are not limited to travel, lodging, meals, medical testing and post-operative evaluation and apply to any transplant performed under AHCCCS coverage, another third-party payer or through self-pay.

E. Multiple Site Listing for Major Organ/Bone Marrow Transplantation

1. If a member seeks to be evaluated for organ or bone marrow transplantation, and "listed" with more than one transplant center in one or more states (other than the primary approved transplant center), AHCCCS will only provide limited coverage. Services will be limited to emergency services. (Expenses for, but not limited to, travel, lodging, meals, medical testing and evaluation for transplantation are not covered.)
2. In the event that a member becomes listed by a facility other than the primary approved transplant center, AHCCCS will not provide coverage for any costs over and above the state-contracted rate for the specific transplant procedures. In addition, facility reimbursement will be available only to HCFA approved transplant centers, and will be limited to the immediate hospitalization for the transplantation surgery and the in-patient post-operative care.

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3. Members must take responsibility for notifying their health plan or program contractor of the arrangements they have made, and for securing and sending appropriate medical records to the transplant case manager of their health plan or program contractor. If the member is receiving services on a FFS basis through the AHCCCS Administration, appropriate medical records must be sent to the transplant case manager in the AHCCCS Office of the Medical Director.

II COVERED TRANSPLANTATIONS

A. Bone Transplantation

This transplantation is not covered as a separate entity but only as a part of another (usually orthopedic) procedure. Routine surgical policies and procedures apply.

B. Bone Marrow and Stem Cell Transplantation

1. Medically necessary bone marrow and stem cell transplantation, including both allogeneic and autologous, is a covered service for AHCCCS members.
2. Allogeneic transplantation is a procedure in which bone marrow or stem cells are obtained from a healthy volunteer donor and intravenously infused into the patient following a marrow toxic or ablative regimen of high dose chemotherapy (HDC) and/or radiotherapy. The purpose of this procedure is to restore normal marrow function.

Autologous transplantation is a procedure in which a portion of a member's bone marrow or stem cells are obtained, placed in storage, and intravenously infused back into the member or eligible person following a marrow-toxic ablative regimen of high dose chemotherapy (HDC) and/or radiotherapy. The purpose of this procedure is the treatment of a malignancy.

3. Medical necessity for bone marrow and stem cell transplantation is established by the following criteria:
 - a. The disease considered for bone marrow and stem cell transplantation is one in which the effectiveness of the proposed marrow ablative therapy has been demonstrated and documented.

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- b. The stage of the disease is such that marrow ablative therapy can affect the outcome.
- c. The Title XIX member has no other conditions which substantially reduce the potential for successful transplantation and subsequent recovery.
- d. Plans for long-term adherence to a disciplined medical regimen are feasible and realistic for the potential candidate for whom the transplant services will be provided.

The feasibility of a potential candidate's adherence to his or her medical regimen is determined through consultation with the Transplant Center where an extensive evaluation of the member, including psychological factors, has been conducted. In addition, consultation may be held with the AHCCCS Medical Director and one of more of the following: the Medical Director of the member's Health Plan or Program Contractor, the member's primary care provider, experts in medical ethics and/or the AHCCCS Bone Marrow/Stem Cell Transplant Expert Committee.

4. Covered Conditions

- a. Allogeneic transplantation has accepted therapeutic value in the management of selected members with, but not limited to, the conditions listed below:
 - (1) Severe combined immune deficiencies (SCID).
 - (2) Aplastic anemia and related disorders.
 - (3) Osteopetrosis.
 - (4) Chronic myelogenous leukemia.
 - (5) Acute non-lymphocytic leukemia.
 - (6) Acute lymphocytic leukemia.
 - (7) Myelodysplastic syndrome.
 - (8) Lysosomal storage disease.
 - (9) Wilms' tumor.
 - (10) Thalassemia.
 - (11) Wiskott-Aldrich Syndrome.
 - (12) Hodgkins Disease.
 - (13) Non-Hodgkins lymphoma.
 - (14) Multiple myeloma.

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- b. Autologous transplantation has accepted therapeutic value in the management of selected members, under 60 years of age with, but not limited to, the conditions listed below:
- (1) Hodgkin's disease.
 - (2) Non-Hodgkin's lymphoma.
 - (3) Acute non-lymphocytic leukemia (in members without a suitable donor of allogeneic transplantation).
 - (4) Acute lymphocytic leukemia (in members without a suitable donor for allogeneic transplantation).
 - (5) Neuroblastoma.
 - (6) Germ cell tumors.
 - (7) Wilm's tumor.
 - (8) Metastatic breast cancer. (Section 7 provides the criteria used in determination of bone marrow transplantation of metastatic breast cancer.)
 - (9) Multiple myeloma.

5. Provider Qualifications:

- a. Bone marrow/stem cell transplants must be provided in a Medicare certified hospital which meets the criteria determined by the American Society of Clinical Oncology and American Society of Hematology as necessary for the safe and successful performance of the procedure. The transplant team must be experienced in this type of procedure.
- b. The provider must agree to cooperate with the International Bone Marrow Transplant Registry and the Cancer Registry of the Arizona Department of Health Services.

6. Components of Service

- a. Allogeneic transplantation involves the following continuum of services:
 - (1) Pre-transplant evaluation and typing of the patient and family members.
 - (2) Search, via designated transplant centers, for a potential unrelated donor if an appropriate match is unavailable through family members.

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- (3) Preparatory regimens including donor marrow harvesting, processing and storage.
 - (4) Marrow infusion and/or stem cell infusion and all related medical care.
 - (5) Post-operative follow-up care and other professional services related to the transplantation, including treatment of complications, outpatient visits and evaluations, medications and diagnostic services. Medications include outpatient self-administered immunosuppressant drugs.
 - (6) Catastrophic reinsurance for up to 100 days post-transplant, including medically necessary lodging and transportation .
- b. Autologous transplantation involves the following continuum of services:
- (1) Pre-transplant evaluation of the member.
 - (2) Preparatory regimens including marrow and/or stem cell harvesting, processing and storage.
 - (3) Marrow and/or stem cell infusion, and all related medical care.
 - (4) Post-operative follow-up care and other professional services related to the transplantation, including treatment of complications, outpatient visits and evaluations, medications and diagnostic services. Medications include outpatient self-administered immunosuppressant drugs.
 - (5) Catastrophic reinsurance for up to 100 days post-transplant, including medically necessary lodging and transportation .
- c. Additional components of service for autologous and allogeneic transplantation :
- (1) Pre-transplant dental evaluation and treatment for oral infection. (The service is limited to diagnosis and elimination of oral infection, and will commence only after the member has been established as an otherwise appropriate candidate.)

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- (2) Room and board for the member and one adult caregiver is provided during the time it is necessary for the member to remain in close proximity to the medical center.
- (3) Transportation for the member and one adult caregiver is provided to and from the medical treatment during the time it is necessary for the member to remain in close proximity to the medical center.

7. Criteria for Use in Determination of Bone Marrow Transplantation for Metastatic Breast Cancer

AHCCCS covers high dose chemotherapy (HDC) plus autologous bone marrow/stem cell transplantation services on an outpatient/inpatient basis for members with metastatic breast cancer for the purpose of providing tumor response, decrease in symptomatology, optimal survival, and improved quality of life for a member who:

- a. Chooses this modality;
- b. Is considered a qualified candidate by an AHCCCS contracted bone marrow/stem cell transplant program;
- c. Could potentially benefit from this therapy; and
- d. Is included in one or more of the following subgroups:
 - (1) At high risk for recurrence following local therapy (mastectomy or lumpectomy and radiotherapy) due to the number of involved axillary lymph nodes (greater than 10), with no evidence of distant metastatic disease; or
 - (2) Diagnosed with palpable axillary lymphadenopathy for which initial surgery is generally precluded in favor of neo-adjuvant chemotherapy followed by salvage mastectomy; and/or diagnosed with other locally advanced metastatic breast cancer presenting with inflammatory breast cancer; or
 - (3) Is a selected member with stage IV metastatic breast cancer, meeting one of more of the following criteria:

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- (i) Soft tissue disease in the chest wall or lymph nodes. The tumor in this clinical circumstance should be amenable to surgical removal, radiation, and/or shown to be chemosensitive following standard dose induction chemotherapy; or
- (ii) Bone only disease with no more than 3 or 4 sites of metastatic involvement in the bones and the sites should be amenable to coverage by radiotherapy ports; or
- (iii) Visceral involvement, only if limited and shown to be responsive to standard dose induction chemotherapy with at least a partial remission (50% shrinkage of tumor sites); or
- (iv) Combinations of (i), (ii) and/or (iii). This will require clinical judgment by the evaluation transplant physician. Each of the requirements indicated in this criteria still apply in this case.

8. Criteria for Use in Determination of Bone Marrow Transplantation for Multiple Myeloma (MM)

AHCCCS covers high dose chemotherapy (HDC) with autologous bone marrow/peripheral stem cell transplantation services and/or allogeneic bone marrow transplantation services on an outpatient/inpatient basis for members with responsive multiple myeloma (MM). This coverage is for the purpose of providing tumor response, decrease in symptomatology, extended duration of remission and optimal survival for members who:

- a. Choose this treatment modality;
- b. Have a diagnosis of responsive MM confirmed by bone marrow aspiration, biopsy and bone x-rays;
- c. Have either stage II or stage III MM, with low tumor burden and/or a low percent of plasma cells synthesizing DNA;
- d. Are considered a qualified candidate by an AHCCCS contracted Bone Marrow Transplant or Stem Cell Transplant facility;
- e. Are not experiencing renal failure; and

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- f. Have a “physiologic age” of 70 or less, except in the case of allogeneic bone marrow transplantation. Allogeneic bone marrow transplantation is currently warranted for those individuals with a “physiologic age” of 50 or less with a human leukocyte-associated antigen compatible donor in the presence of the following; good performance status, low tumor burden and responsiveness to previous chemotherapy.

C. Cornea Transplantation

Routine surgical policies and procedures apply.

D. Heart Transplantation

1. Medically necessary heart transplantations and related services are covered for AHCCCS members.
2. Heart transplantation is a procedure in which a heart is harvested from a cadaveric human donor and transplanted into the patient. Only human heart transplantation is covered.
3. AHCCCS covers ventricular assist devices (VAD's) as a bridge to heart transplantation under the circumstances specified in the AHCCCS medical policy manual. AHCCCS does not currently cover VAD's for use on a permanent basis. Additionally, AHCCCS assumes no financial responsibility for costs related to an artificial heart as a permanent replacement for a human heart or as a bridge to transplant.
4. Medical necessity for heart transplantation is established by the following criteria:
 - a. The potential transplant recipient has end-stage heart disease.
 - b. The prognosis for survival is less than 1 year if the transplantation is not received.
 - c. The transplantation is considered for a disease in which the effectiveness of the proposed transplantation has been demonstrated and documented.
 - d. The stage of the disease is such that the transplantation can affect the outcome.

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- e. The potential for successful transplantation and subsequent recovery is not significantly compromised by other conditions including, but not limited to:
 - (1) Severe lung disease, except as appropriate for heart-lung transplantation addressed in AHCCCS medical policy.
 - (2) Malignant disease.
 - (3) Stroke or refractory hypertension.
 - (4) Chronic pulmonary embolism or recent pulmonary infarction, except as appropriate for heart-lung transplantation and addressed in AHCCCS medical policy.
 - (5) Active infection.
 - (6) Irreversible disease of a major organ system.
- f. Plans for long-term adherence to a disciplined medical regimen are feasible and realistic for the potential candidate to whom the transplantation services will be provided.

The feasibility of a potential candidate's adherence to his or her medical regimen is determined through consultation with the Transplant Center where an extensive evaluation of the member, including psychological factors, has been conducted. In addition, consultation may be held with the AHCCCS Medical Director and one of more of the following: the Medical Director of the member's Health Plan or Program Contractor, the member's primary care provider, experts in medical ethics and/or the AHCCCS Heart Transplantation Expert Committee.

5. Components of Service

Heart transplantation involves the following services:

- a. Candidate assessment and pre-transplantation evaluation (on an inpatient or outpatient basis).